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AMBU A/S, AMBU INC., AND AMBU LTD.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

THE LARYNGEAL MASK COMPANY LTD. and LMA NORTH AMERICA, INC.,

Plaintiffs,

v.

AMBU A/S, AMBU INC., AND AMBU LTD.,

Defendants,

AND RELATED COUNTERCLAIMS.

Case No. 3:07-cv-01988 DMS (NLS)

Jury Trial Demanded

DEFENDANTS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OF INVALIDITY FOR LACK OF WRITTEN DESCRIPTION

Date: September 25, 2009
Time: 1:30 pm
Courtroom: 10, 2nd Floor
Judge: The Honorable Dana M. Sabraw

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I. STATEMENT OF RELIEF REQUESTED

Ambu brings this motion for summary judgment that each of the asserted claims 1-6 of U.S. patent No. 7,156,100 ("the '100 patent") is invalid for lack of written description under 35 U.S.C. § 112, ¶ 1.

II. INTRODUCTION

The '100 patent is invalid under 35 U.S.C. section 112 because there are at least two critical disconnects between what LMA disclosed in the specification of the '100 patent, and what it claimed. Each disconnect provides a separate and independent basis for determining that the asserted claims do not have adequate support in the specification. First, the patent claims at issue require that part of the cuff of the claimed laryngeal mask be thicker and stiffer than the rest of the cuff. There is no teaching in the patent specification of an embodiment that accomplishes this. Accordingly, the asserted claims are invalid.

Second, at LMA's request, the patent claims in this case have been construed to cover both the disclosed distal rib formation, which is a physical extension of the backplate (the rigid area that is surrounded by the cuff), as well other non-disclosed designs without this feature. Accordingly, the claims do not support the full scope of claims. In its zeal to capture Ambu's stiffener, which does not extend from any backplate, LMA has thus invited the invalidity of its own patent.

Section 112, often referred to as the "written description" requirement, aims to protect the public from overzealous patent holders, like LMA here, who attempt to claim that which they did not invent. Simply put, section 112 requires that the full scope of the claimed invention is described in the specification such that it can be ascertained that the inventor was in possession of the invention as claimed. Patents that fail to meet the requirements of section 112 are invalid.

Invalidity under section 112, based on the absence of a complete written description of the claims as drafted and construed, is ripe for determination by the Court on a motion for summary judgment. There can be, of course, no genuine dispute regarding the content of the '100 patent's specification. Expert testimony cannot be used to vary that intrinsic record, and in fact under

either construction advanced by the experts, the same result obtains – the asserted claims are invalid. Thus, the only issues to be resolved by the Court are those of law: the scope of the claims and the application of Federal Circuit precedent on written description.

III. STATEMENT OF RELEVANT FACTS

A. Prosecution of the '100 Patent

The application for the '100 patent was filed by Dr. Archibald Brain on October 5, 1999. The invention claimed in the '100 patent relates to a laryngeal mask airway device, an artificial airway device used in anesthesia and emergency situations [Lampotang Decl. Ex. B, '100 patent, col. 1, lines 10-14.] Generally, a laryngeal mask comprises an airway tube and a mask portion containing an inflatable cuff, and the device is inserted into a patient's throat when the cuff is fully deflated. [*Id.* at col. 1, lines 20-22; Figure 1.]

When the application was originally filed, and for two years thereafter, LMA sought to obtain patent claims that related to several different features of a laryngeal mask other than those that are presently claimed, such as an indentation structure for directing the backplate of the device during insertion, an aperture bar to support the epiglottis after placement of the device, and an inflatable back cushion. These limitations were sought either alone or in combination with a backplate extension in which the bowl of the backplate had a longitudinal distal rib. The tactic of claiming minor improvements in order to try to extend LMA's patent monopoly on the original laryngeal mask device, culminated on November 7, 2001, when LMA received a communication from the examiner indicating that the claims directed to the backplate extension were allowable. [*See* Declaration of Darryl M. Woo in Support of Defendants' Motion for Summary Judgment of Invalidity on Written Description Grounds ("Woo Decl."), Ex. M, '100 patent File History, June 17, 2005 Amendment at 4.]

On February 12, 2002, LMA then abandoned those allowed claims in favor of attempting to patent a different feature, namely the indentation feature. [*See* Woo Decl. Ex. N, '100 patent File History, February 12, 2002 Amendment at 5.]

Ultimately, seven and half years after beginning prosecution and shortly after LMA was assigned a different patent examiner, LMA drafted claims directed to the presently claimed

invention(s). The originally filed claims that were drawn to the rib as a backplate extension all recited a limitation, "said bowl [of the backplate] having a longitudinal distal rib for longitudinally supporting the distal region of said main-cuff." [*See* Woo Decl. Ex. O, '100 patent File History, Oct. 5, 1999 Application at 19-20 (claims 1-4).] In April 2006, the applicant filed an amendment to cancel all prior claims and to propose a new set of claims which included new claims that were broader than those previously prosecuted and no longer expressly recited a limitation requiring that the longitudinal distal rib be an extension of the backplate. [*See* Woo Decl. Ex. P, '100 patent File History, April 24, 2006 Amendment at 2-3.] Instead, these proposed claims recited a limitation with a cuff wall with "at least a first portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff." [*Id.*] The claims issued after the Examiner made an amendment to limit the "thicker and stiffer" portion of the cuff to the posterior wall of the cuff. [*See* Woo Decl. Ex. Q, '100 patent File History, Aug. 23, 2006 Notice of Allowance at 2.]

B. The Specification of the '100 Patent

During this lengthy patent prosecution, of course the substance of LMA's patent specification did not change. That specification did recite that one problem purportedly addressed by the disclosed invention was that, during insertion of the device, the distal end of the deflated cuff may occasionally fold back on itself, resulting in trauma to the patient's throat and obstruction of the airway. [Lampotang Decl. ¶ 49; Ex. B, '100 patent at col. 1, lines 27-43.] The specification taught to address that problem by the use of a reinforcing rib, which is the improvement that LMA originally tried to claim:

> The present invention seeks to eliminate the disadvantages associated with such undesirable insertion by minimizing the risk of the deflated cuff formation becoming folding over on itself during the insertion procedure. This is achieved by incorporating into the cuff at its distal end a reinforcing rib which serves to stiffen the leading end of the LMA-device during the course of the procedure for its insertion.

[*Id.* at col. 1, lines 48-55.] The invention was further described as preferably making the distal rib by extending a portion of the relatively rigid backplate: "In a preferred aspect, the mask

structure or backplate which is of a more rigid material than that of the soft and inflatable cuff formation has its back extended to the distal end of the cuff, in order to form the reinforcing rib." This "preferred aspect" describes a laryngeal mask having the backplate extended to the distal end of the cuff to form the reinforcing rib. [Lampotang Decl. ¶ 51; Ex. B, '100 patent at col. 1, lines 64-67.] It then explains that a laryngeal mask incorporating "such a reinforcing rib" has a number of advantages over the prior art. [*Id.* at col. 2, lines 1-12.] Those include that "the reinforcing rib largely eliminate[s] the likelihood of the distal end of the deflated cuff formation folding over on itself during insertion of the LMA-device into the patient's throat." [*Id.*]

The '100 specification goes on to describe and depict two embodiments of the reinforcing rib, both involving a rib that extends from the backplate. The first embodiment has a reinforcing rib formed by extending the backplate through the interior of the distal region of the cuff. [*Id.* at col. 6, lines 31-33 ("The backplate 52 has a one-piece, integral spoon-shape including a bowl 90 . . . . The bowl 90 also has an elongate integral reinforcing distal rib 105."); col. 6, lines 3-10 ("The distal rib 105 extends through the interior of the main-cuff 55 to the distal surface of the distal region 60.").] This is shown below in Figure 5 and 6:

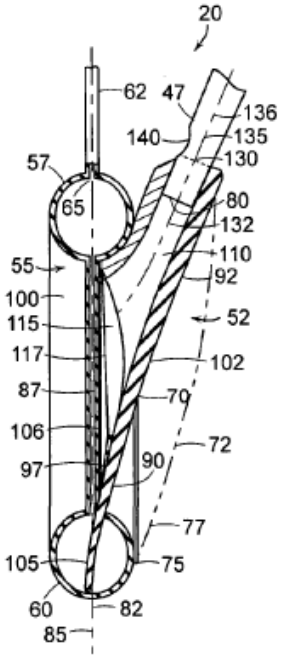

FIG. 5

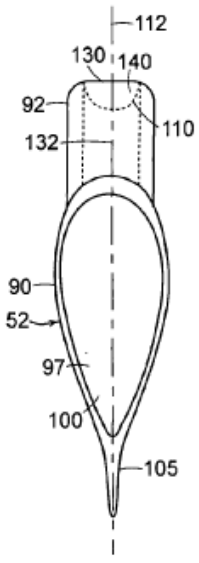

FIG. 6

Here, the "backplate 52 as a one-piece, integral spoon-shape including a bowl 90 and an external

tube-joint 92." [*Id.* at col. 6, lines 3-5.] The patent contains a detailed description of the distal rib, 105:

> When the backplate 52 is attached to the main-cuff 55, the distal rib 105 pierces the proximal surface of the distal region 60. The edges of the main-cuff 55 in the distal region 60 surrounding the distal rib 105 are hermetically sealed to is such that the enclosure of the main-cuff is defined in part by the distal rib. The distal rib 105 extends though the interior of the main-cuff 55 to the distal surface of the distal region 60."

[*Id.* at col. 6, lines 26-34.] This embodiment thus teaches a distal rib that extends from the backplate to pierce the interior of the cuff.

The second embodiment uses a distal rib that projects on top of, rather than through, the cuff. [Lampotang Decl. ¶ 52; Ex. B, '100 patent at col. 7, line 65 – col. 1, line 1, refering to "the distal rib 105a of the backplate 52a . . . applied to the posterior surface of the distal region 60a of the main-cuff 55a."] This is shown below in figures 10 and 11:

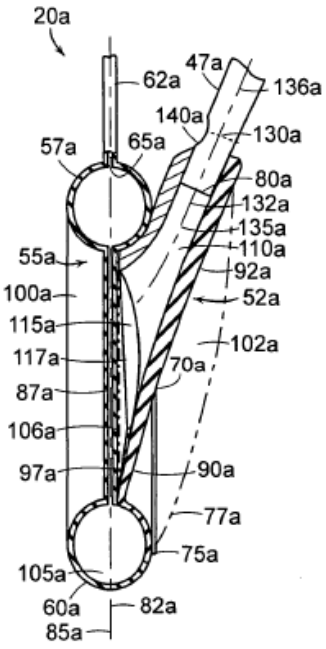

FIG. 10

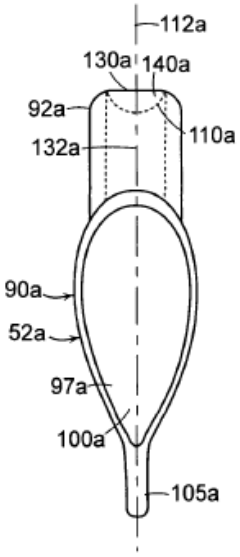

FIG. 11

As the patent explains,

> The backplate 52a is similar to the backplate 52 illustrated in Figs.

> 5 and 6 except that the distal rib 105a of the backplate 52a is applied to the posterior surface of the distal region 60a of the main-cuff 55a, as shown in Fig. 10. … The distal rib 105a does not pierce the posterior surface of the distal region 60, in contrast to the embodiment show in Fig. 5, and is therefore separate from the interior of the main-cuff 55a. The distal rib 105a may be effectively constituted by a thickening of the posterior wall of the distal region 60a of the inflatable main-cuff 55a and, as shown, forms a distal extension of the bowl 90a of the backplate 52a. The distal rib 105a has a downturned profile by being incorporated into the posterior surface of the main-cuff 55a. The distal end of the distal rib 105a is spatulate.

[*Id.* at col. 7, line 65 – col. 8, line 16.] The patent goes on to describe how "The distal rib 105a may not be readily visible because it may appear to blend in with the posterior wall of the distal region 60. The spatulate of the distal portion of the distal rib 105a does not present any sharp edges or corners to the throat 22 the patient during insertion…." [*Id.* at col. 8, line 63 – col. 9, line 3.]

Thus, the only teachings in the '100 patent are of ribs that extend from the backplate and either lie along the surface of the cuff or extend into its interior. No other embodiments are disclosed.

C. The Scope of the Asserted Claims

LMA accuses Ambu of infringing claims 1 through 6 of the '100 patent. The only independent claim, claim 1, recites as follows:

A laryngeal-mask airway device comprising:

> a backplate defining a passage;
>
> an inflatable cuff, the cuff defining a distal region and a central opening at least when inflated, the cuff being attached to the backplate, the cuff being insertable through a mouth of a patient to an inserted location within the patient, an airway extending from a laryngeal inlet of the patient, through the central opening, to the passage when the cuff is inflated and at the inserted location, ***at least a portion of the posterior portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff***.

[*Id.* at col. 10, lines 15-26 (emphasis added).]

Dependent claims 2-4 include further limitations with respect to the "portion of the posterior portion of the wall." Claim 2 requires that portion to be "more compliant than the backplate," whereas claims 3 and 4 require it to form a "distal rib" and a "longitudinal distal rib," respectively. [*Id.* at col. 10, lines 27-34.] Dependent claims 5 and 6 do not include any additional limitation related to the cuff stiffener limitation. [*Id.* at col. 10, lines 35-44.]

The asserted claims that do not expressly recite that the cuff stiffener is extended from the backplate[1] were not filed with the original application; rather, they were added years later during prosecution. The originally filed claims that were drawn to an invention having a cuff stiffener all recited a limitation, "said bowl [of the backplate] having a longitudinal distal rib for longitudinally supporting the distal region of said main-cuff." [Woo Decl. Ex. O, '100 patent File History, Oct. 5, 1999 Application at 19-20 (claims 1-4).] In April 2006, the applicant filed an amendment that cancelled all prior claims and proposed a new set of claims which no longer recited an express limitation requiring the backplate to have a longitudinal distal rib. ['100 Patent File History, April 24, 2006 Amendment at 2-3.] Instead, these proposed claims recited the more vaguely worded limitation, "at least a first portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff." [*Id.*] The claims issued after an amendment by the Examiner to limit the "thicker and stiffer" portion of the cuff to the posterior wall of the cuff. ." [Woo Decl. Ex. Q, '100 patent File History, Aug. 23, 2006 Notice of Allowance at 2.]

In 2004, Ambu started marketing one of the accused products, the Ambu Laryngeal Mask[2] that had a broad reinforcement on part of the cuff. By March 2005, LMA had noticed this product, which competed with the LMA Classic and Unique, and described it in LMA's own training materials as having "an extra soft cuff with a reinforced tip to prevent folding." [*See id.*] [*See* Woo Decl. Ex. R, LMA Training Module, dated March 2005 at LMA00006419.] Shortly

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[1] As the Court is aware from the claim construction briefing, Ambu believes that the claims should have been construed to include the limitation that the stiffener is an extension of the backplate.

[2] The Ambu Laryngeal Mask, now marketed under the trade name AuraOnce, has since been held not to infringe LMA's patent. *See* Order Granting Defendants' Motion for Partial Summary Judgment of Non-Infringement, Docket No. 224, June 25, 2009.

thereafter in April 2006, as noted in the discussion of the file history above, LMA filed an amendment that cancelled all prior claims and proposed a new set of claims which no longer recited an express limitation requiring that the longitudinal distal rib be an extension of the backplate. [*See* Woo Decl. Ex. P, '100 Patent File History, April 24, 2006 Amendment at 2-3.] As LMA has admitted, LMA itself has never used this product configuration. [*See* Woo Decl. Ex. S, LMA's Response to Interrogatory Nos. 4, 6.]

On March 17, 2009, the Court issued an Order construing the disputed claim terms of the '100 patent, including the limitation "at least a portion of the posterior portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff." [Order Construing Patent Claims, Docket No. 171.] Two aspects of the Court's construction are relevant to this motion. First, the Court adopted LMA's contention that the "thicker and stiffer" part of the cuff need not be attached to the backplate. [*Id.* at 9:3-5 ("Accordingly, the Court declines to find that the "thicker and stiffer" portion of the cuff must be connected to the backplate.").] Second, it declined to place further constraints on the location of the "thicker and stiffer" limitation, holding that it must be construed according to its plain meaning. [*Id.* at 9:6-16.]

The parties recently exchanged expert reports, and are in the process of completing expert depositions. [Woo Decl. ¶ 2.] LMA for some reason designated more than one expert to testify about the validity of the '100 patent, William Rosenblatt and Herb D'Alo.[3] Each claimed expert has confirmed that they are taking the position that when the patent claim recites "at least a portion of the posterior portion of the wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff," that this requires that the materials used in the cuff wall must be thickened (and that thickening the cuff by placing glue on it or by attaching another material to it is not reached by the claims). For example, one of LMA's "experts," Mr. D'Alo, owns a company that supplies airway products to LMA. He testified that the asserted claims of the '100 patent do not cover either Figure 5 or Figure 10 from the patent. [Woo Decl. Ex. T, D'Alo Depo.

[3] This designation of cumulative experts is improper, and will be the subject of future motions practice should this matter proceed to trial.

at 112:1-116:15.] Similarly, LMA's second expert, Dr. Rosenblatt, stated both that in his view the actual cuff wall has to be thicker and stiffer, and that none of the images in the patent teach that (though he said he was unsure what one figure taught). [Woo Decl. Ex. U, Rosenblatt Depo. at 102:16-21; 121:16-22 and 126:16-127:11.]

While Ambu disagrees with LMA's experts' interpretation, in the event that the Court adopts LMA's interpretation, the patent should be held invalid for lack of written description.

IV. ARGUMENT

A. Summary Judgment of Written Description is Available

Summary judgment is as appropriate in a patent case as in any other case. Fed. R. Civ. P. 56(c); *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1117 (Fed. Cir. 1985). While written description is a question of fact, it is amenable to summary judgment if no reasonable fact finder could return a verdict for the non-moving party. Indeed, the Federal Circuit has routinely upheld summary judgment of invalidity on written description grounds. *See, e.g., PowerOasis v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306-1311 (Fed. Cir. 2008) (disclosure of multiple embodiments of a user interface as part of a vending machine did not provide written description for claims reciting a user interface located apart from the vending machine); *ICU Medical, Inc. v. Alarias Medical Systems, Inc.*, 558 F.3d 1368, 1376-79 (Fed. Cir. 2009) (description of a medical valve operated with a spike did not provide adequate written description for claims covering spikeless medical valves); *LizardTech v. Earth Resource Mapping Pty Ltd.*, 424 F.3d 1336, 1344-45 (Fed. Cir. 2005) (description of one method for creating a seamless discrete wave transform (DWT) did not entitle the inventor to claim any and all means for achieving that objective); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159-60 (Fed. Cir. 1998) (specification disclosing only conical shaped cup implants failed to support claims reciting a generic cup shape). Further, conclusory statements of experts are insufficient to raise a genuine issue of material fact to defeat a summary judgment of invalidity for lack of written description. *See PowerOasis*, 522 F.3d at 1310.

It is not uncommon for a patent to be held invalid for failure to meet the written description requirement based solely on the language of the patent specification. *See Univ. of Rochester v.*

G.D. Searle & Co., 358 F.3d 916, 927 (Fed. Cir. 2004); *PIN/NIP, Inc. v. Platte Chemical Co.*, 304 F.3d 1235 (Fed. Cir. 2002). Under the patent law, a patent specification must provide a written description of the invention. 35 U.S.C. § 112, ¶ 1. A patent claim that either has no support in the specification, or is so broad that it encompasses substantial subject matter that was not disclosed in the specification, is invalid.

A touchstone requirement under section 112 is that the patentee show that he was "in possession" of the invention as claimed. *PowerOasis*, 522 F.3d at 1306. To show that one is "in possession" of the invention, the patent must describe all its claimed limitations. *Id*. "The written description requirement is not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure. Rather, it is a question whether the application necessarily discloses that particular device." *Id.* (quoting *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)).

The written description also limits the breadth of the claims that can be obtained. "The purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.'" *ICU Medical* 558 F.3d at 1376 (quoting *Univ. of Rochester* 358 F.3d at 920). The mere description of one embodiment of the claimed subject matter does not entitle a patentee to broadly claim beyond the scope of the invention(s) disclosed . *See, e.g., LizardTech* 424 F.3d at 1346 ("[A] patentee cannot always satisfy the requirements of section 112, in supporting expansive claim language, merely by clearly describing one embodiment of the thing claimed.") "To satisfy the written description requirement for a claimed genus, a specification must describe the claimed invention in such a way that a person of skill in the art would understand that the genus that is being claimed has been invented, not just a species of the genus." *Carnegie Mellon Univ. v. Hoffmann-La Roche, Inc.*, 541 F.3d 1115, 1124 (Fed. Cir. 2008).

B. Ambu Is Entitled to Summary Judgment That the Asserted Claims Are Invalid for Lack of Written Description.

1. The '100 Patent Fails to Adequately Describe That the Posterior Wall of the Cuff Itself Is Thicker and Stiffer Than Other Portions of the Cuff.

To satisfy the written description requirement, every claim limitation must be supported by the specification. *PowerOasis*, 522 F.3d at 1306 (quoting *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997)) ("While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification."). The specification need not contain precisely the same words as recited in the asserted claims but it must convey possession of the invention. *Id.*

Here, the parties are not in agreement over the application of the posterior cuff reinforcement limitation of claim 1. LMA submits that it requires a portion of the cuff wall itself, and not merely an extension of the backplate, be "thicker and stiffer" than other portions of the cuff. [Woo Decl. Ex. T, D'Alo Depo. at 112:1-116:15; Ex. U, Rosenblatt Depo. at 102:16-21, 121:16-22 and 126:16-127:11.] Indeed, LMA would urge that asserted claims 1-6 do not include any of the specification's disclosed embodiments where the cuff is thickened and stiffened by an extension of the backplate. [D'Alo Depo. at 112:1-116:15; Rosenblatt Depo. at 102:16-21, 121:16-22.]

On the other hand, Ambu submits that a cuff wall can be reinforced, and made "thicker and stiffer" within the meaning of claim 1, either by thickening the material of the cuff in the specific area, or by adhering to the cuff another material, such as glue, a rib such as is taught in the two patent drawings, or other reinforcing material. [Dr. Lampotang Decl. ¶ 19.] Interestingly, despite LMA's "plain meaning" interpretation of Claim 1, Mr. D'Alo conceded that if one were to glue a plywood board to a room wall, that would make the wall thicker and stiffer. [D'Alo Depo. at 68:18-69:7.] Both Mr. D'Alo and Dr. Rosenblatt further conceded that the patent claims did not require any particular manufacturing methodology to make the cuff wall thicker and stiffer, thus allowing for making the cuff wall stiffer and thicker by, as taught by the

'100 specification, extending a rib from the backplate to reinforce the distal tip of the cuff. [*Id.*]

Ambu submits that if the Court determines that LMA is correct, the Court should grant summary judgment of invalidity for lack of written description.[4] First, as set forth above at pages 4-6, each of the Figures of the '100 patent recites a distal rib that extends from the backplate, either through or over the cuff. None of them shows a reinforcement of the cuff wall that is achieved without use of a backplate extension.

Unable to identify any product designs in the '100 patent that meet the claim limitation as they are applying it, LMA resorts to trying to conjure a third embodiment in the specification where none exists. What LMA does is point primarily to a single sentence in the '100 specification that states, in reference to Figure 10, that:

> The distal rib 105a may be effectively constituted by a thickening of the posterior wall of the distal region 60a of the inflatable main-cuff 55a and, as shown, forms a distal extension of the bowl 90a of the backplate 52a.

[Lampotang Decl. Ex. B, '100 patent, col. 8, lines 9-12.] The plain language of the complete sentence, however, states that the rib is a "distal extension of the bowl 90a of the backplate 52a." The sentence furthermore refers to the "second" embodiment that places the distal rib extension of the backplate along the surface of the cuff wall, as shown in Figures 10 and 11. Also, this sentence is contained in a paragraph beginning at col. 7, line 62, which refers to the second embodiment for which two views are shown in Figures 10 and 11:

[4] Whether or not LMA's claim construction is correct, LMA's patent is also invalid over the prior art. This is spelled out in more detail in Ambu's contemporaneous motion for summary judgment on anticipation or obviousness. [*See* Defendants' Motion for Summary Judgment of Invalidity for Anticipation and Obviousness.]

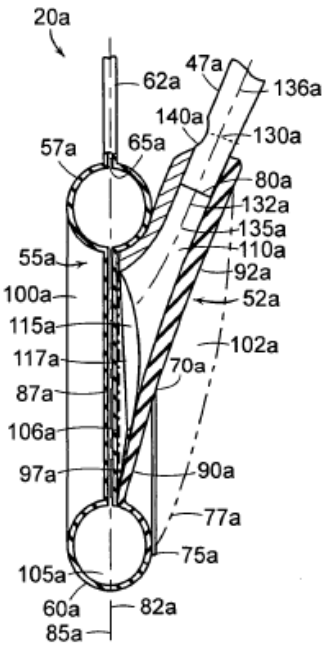

FIG. 10

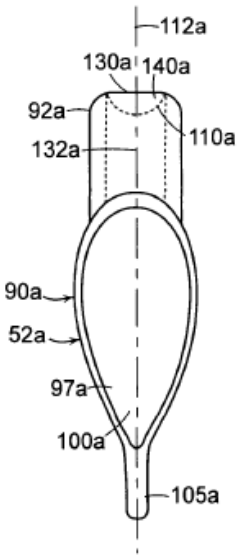

FIG. 11

The patent itself explains that Fig. 10 is a "cross-sectional view of a second embodiment of the device of Fig. 1…." [*Id.* at col. 3, lines 51-53.] Figure 11 is described as "an anterior plan view of the backplate removed from the device shown in Fig.10." [*Id.* at lines 55-56.] The sentence at column 8, lines 9-12 refers to distal rib 105a, and the description of figures 10 and 11 explain that "The backplate 52a is similar to the backplate 52 illustrated in Figs. 5 and 6 *except that the distal rib 105a of the backplate 52a is applied to the posterior surface of the distal region 60a of the main-cuff 55a, as shown in Fig. 10*. The distal rib 105a has a concave anterior surface corresponding to the adjoining convex posterior surface of the distal region 60a thereby limiting the radial clearance between the distal region and end 60a, 105a. " [*Id.* at col. 7, line 65 to col. 8, line 5 (emphasis added).] Thus, these drawings show that an extension of the backplate is placed on top of the cuff in order to reinforce it.

As such, there is no third embodiment taught in the patent. The sentence cited by LMA in support of its argument is about a second backplate extension embodiment, not some phantom embodiment where the cuff material itself has to be made thicker and stiffer. LMA's argument that a sentence fragment in the sentence quoted above – that first portion of the sentence that

states that as a result of giving the distal rib a shape similar to the shape of the cuff wall, the wall in that region is thickened – should be rejected.

LMA's argument is just like that made by the patent holder in *Agilent Technologies, Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1380-83 (Fed. Cir. 2009), which argument was rejected by the Federal Circuit, holding that the patent claims were not supported by the specification at issue. *Agilent* involved a patent on preparing a fluid sample used in certain types of genetic testing. The claims required that this be done in a closed chamber and that bubble mixing be done. The only mention in the specification of bubbles was within an embodiment that was an open, not closed, system, and the Court held that where such references to bubbles were "inextricably wedded" to the specified open embodiments, they did not support the claim. *Id.* at 1382. Here, the reference to cuff thickening is similarly inextricably wedded to the embodiment using a distal rib that extends over the surface of the cuff wall, and cannot be read as teaching a third embodiment that supports the claims as construed by LMA's experts.

Similarly, in *PowerOasis*, the Federal Circuit affirmed a summary judgment of invalidity for anticipation on the ground that the original application, which the patentee relied on for priority, disclosed only a "customer interface" as a display on a vending machine, but the claims were construed to cover an interface apart from the vending machine. 522 F.3d at 1311. While the original application disclosed multiple embodiments of the "user interface," all such embodiments described the user interface as part of a "unitary vending machine apparatus." *Id.* at 1309. There was no disclosure of a user interface "separate from the vending machine itself." *Id.* The court found that it was immaterial that a skilled person in the art would know how to substitute a laptop computer for the user interface that is part of the unitary vending machine, because "[o]bviousness simply is not enough; the subject matter must be disclosed to establish possession." *Id.* at 1310.

If the claims, as LMA contends, require that the material of the cuff wall itself be thickened to the exclusion of any use of a backplate extension, there is no teaching of such in the specification and the claims are invalid. Moreoever, LMA cannot defeat summary judgment by pointing to the opinions of its experts, as cited above. In *PowerOasis*, the Federal Circuit held

that an expert's declaration failed to raise a genuine issue of fact as to whether a specification disclosed a customer interface located on a customer laptop, where the declaration pointed to only figures and discussions showing a user interface located on a vending machine. Similarly, here, LMA's experts point to nothing but an embodiment that does not support their claims.

Accordingly, there is no genuine issue of material fact that the specification fails to provide adequate written description that the posterior wall of the cuff itself has a portion "thicker and stiffer" than other portions of the cuff, and summary judgment is appropriate. In addition, because the dependent claims depend from invalid claim 1, they are invalid as well. *See National Recovery Techs. Inc. v. Magnetic Separation Sys. Inc*., 166 F.3d 1190, 1198 (Fed. Cir. 1999) (holding that, for purposes of 35 U.S.C. § 112, paragraph 1, dependent claims stand or fall with the claim from which they depend) (citing § 112, paragraph 4).

2. The '100 Patent Fails to Provide Written Description for the Full Scope of the Claimed Genera.

To satisfy the written description requirement, the '100 patent specification must fully describe each limitation of the asserted claims. *See id.* at 1306. While the specification only describes the use of a narrow reinforcing rib extended from the backplate to the distal end of the cuff, the asserted claims, as construed, recite a limitation that broadly encompasses a cuff stiffener that is not part of the backplate.

The asserted claims 1 through 6 recite the limitation that "at least a portion of the posterior portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff". [Lampotang Decl. Ex. B, '100 patent, col. 10, lines 24-26.] During claim construction, LMA urged and obtained a broad construction of this limitation. [Order Construing Claims at 9.] In particular, the Court held that the claim does not require that the "thicker and stiffer" portion of the cuff be connected to the backplate. [*Id.* at 8-9.] Instead, the "thicker and stiffer" portion can be located anywhere on the posterior wall of the cuff in a region distal to the backplate.[5] [*Id*.]

[5] The Court has construed the term "distal region" as "the region of the cuff distal to the backplate, *i.e.*, the leading edge of the cuff." [Order Construing Claims at 8.]

There is no teaching, however, of such a "disconnected" stiffener. The '100 patent specification repeatedly and consistently describes a cuff stiffener as a reinforcing rib that is an integral part of the backplate extending to the distal region of the cuff. The section of the specification describes two specific embodiments, both having a backplate extended to the distal end of the cuff to form a reinforcing rib. The first embodiment is described as having a "backplate 52 [that] has a one-piece, integral spoon-shape including a bowl 90" which in turn "has an elongate integral reinforcing distal rib 105." [Lampotang Decl. Ex. B, '100 patent, col. 6, lines 3-4, 9-10.] As illustrated by Figures 5 and 6, set forth above on page 4, 105 is a distal extension of the backplate 52 extending through the interior of the cuff.

The second embodiment is described as having a backplate 52a "similar to the backplate 52 [of the first embodiment] except that the distal rib 105a of the backplate 52a is applied to the posterior surface of the distal region 60a of the main-cuff 55a." [*Id.* at col. 7, line 65 – col. 8, line 1 (emphasis added).] This description makes clear that, just like the distal rib 105 of the first embodiment, the distal rib 105a of the second embodiment is also an integral part of the backplate 52a. In addition, figures 10 and 11 set forth above at page 13, depicting the second embodiment and related text, show that the distal rib 105a is an extension of the backplate.

LMA's experts cannot raise a triable issue of fact on this point. *See MyMail, Ltd. v. Am. Online, Inc.*, 476 F.3d 1372, 1378 n.1 (Fed. Cir. 2007) (holding that expert testimony that contradicts the specification cannot raise a genuine issue of material fact to defeat summary judgment). Indeed, LMA's designated expert, Mr. D'Alo (President and CEO of LMA supplier M.E.M., Incorporated), admitted that the '100 specification does not teach any embodiment where a posterior cuff reinforcement is not connected to the backplate. [*See* Woo Decl. Ex. T, D'Alo Depo. at 104] ("Q. Does the '100 patent teach any embodiment where the posterior cuff reinforcement element is not connected to the backplate? A. ^ Check. I don't believe it teaches it."). Second, LMA's other designated expert, Dr. Rosenblatt, attempted to disagree, but was able to identify only the same sentence fragment referred to above as possibly teaching any third alternative. [Woo Decl. Ex U, Rosenblatt Depo. at 122:2-14.] As noted above, however, that sentence fragment, read in its entirely, refers instead to the second embodiment where the

reinforcement is an extension of the backplate placed along the posterior surface of the cuff. (*See supra* at p. 12.)

Where, as here, the specification only describes subject matter with a specific feature, but the patent claim has been construed as covering much broader subject matter, the patent claim is invalid for lack of written description. Here, the posterior cuff reinforcement limitation has been construed as having broad scope, but the '100 specification only teaches embodiments where the posterior cuff reinforcement is connected to the backplate. The mere description of one species within the limitation (backplate extensions as a means of thickening and stiffening a cuff) is not enough to support a broad genus claim covering any and all species of that limitation (all manners of cuff thickening and stiffening), *see LizardTech*, 424 F.3d at 1346, much less LMA's tightrope walking, which attempts to construe claims 1-6 as not including any form of thickening through backplate extension, but only thickening (and stiffening) of the cuff wall itself.

Under these circumstances, summary judgment is appropriate. The Federal Circuit has repeatedly upheld summary judgment of invalidity on written description grounds where the specification describes only a subject matter with a specific feature, but the claims refer to the subject matter generically, covering those with and without that specific feature. *See, e.g.*, *PowerOasis*, 522 F.3d at 1306-1311; *ICU Medical*, 558 F.3d at 1376-79; *LizardTech*, 424 F.3d at 1344-45; *Tronzo* 156 F.3d at 1159-60.

On strikingly similar facts, in *ICU Medical*, the Federal Circuit affirmed a summary judgment of invalidity for lack of written description where the patent specification described only medical valves with spikes but the claims at issue did not include a spike limitation. 558 F.3d at 1376-79. These "spikeless claims" would encompass medical valves generically covering valves that operate with a spike and those that operate without spike. *Id.* at 1378. As the court noted, these "spikeless claims" were not filed with the original application on which the asserted claims relied on for priority; rather, they were added years later during prosecution. *Id.* at 1377. The court rejected the patentee's argument that figures and description including spikes somehow showed that the inventor possessed a medical valve that operated without a spike. *Id.* at 1378. Furthermore, the court held that the fact that a spikeless valve might be obvious in view of a

disclosed embodiment was insufficient to satisfy the written description requirement. *Id.* at 1378-79 ("[A]n applicant complies with the written description requirement by describing the invention, with all its claimed limitations, not that which makes it obvious.") (internal quotation omitted).

Similarly, here the '100 specification describes two embodiments of the invention, each of which uses a backplate extension. As such, the specification does not provide written description for the later-filed claims that cover a cuff stiffener not extended from the backplate. *See id.; see also ICU Medical*, 558 F.3d at 1376-79 (description of a medical valve operated with a spike did not provide adequate written description for claims covering spikeless medical valves); *Tronzo.*, 156 F.3d at 1159-60 (specification disclosing only a conical shaped cup implant failed to support claims reciting a generic cup shape).

Indeed, the specification makes clear that the advantages of the claimed invention over the prior art are attributed not to a generic reinforcing rib, but to the one specifically described in the "preferred aspect." Immediately following the description of the preferred aspect of a laryngeal mask with a reinforcing rib extended from the backplate, the specification touts the laryngeal mask "incorporating such a reinforcing rib" as having a number of advantages over the prior art in solving the fold over problem. [*See* Lampotang Decl. Ex. B, '100 patent, at col. 1, line 64 – col. 2, line 3.] *See also Tronzo*, 156 F.3d at 1159 (holding that claims reciting cup implants with a generic shape were invalid for lack of written description where the specification touted the advantages of a conical shaped cup over the prior art and described the conical shape design as an "extremely important aspect" of the invention).

Moreover, the thicker and stiffer reinforcement of the cuff wall must extend from the backplate to the cuff in order for the invention to achieve its purported goal. The '100 patent purportedly teaches solving the problem of cuff folding over through an extension of the backplate. [*See* Dr. Lampotang Decl. ¶ 19.] If there is a gap in the reinforcement between the distal end of the backplate and the cuff, then the fold over will occur at the gap, and the goal of the invention would not be achieved. [*See id.*] In fact, Mr. D'Alo admits that a person of ordinary skill in the art in 1998 who was trying to reinforce the cuff to prevent folding over would

not choose to take material away from the cuff reinforcement to provide a gap between the backplate and the cuff. [*See* Woo Decl. Ex. V, D'Alo Aug.6 Depo. at 208:17-209:6]:

> Q. . . . Which way would be more intuitive to a person of ordinary skill, back in '98, if the purpose was to prevent foldover? Would they find it intuitive to choose – to have a gap or not to have a gap?
>
> Mr. Noah: The same objection.
>
> A. If I'm trying to reinforce something, I would normally not try to achieve that by taking material away, which would be providing a gap.
>
> Q. So, a person of ordinary skill would choose not to have a gap. Yes?
>
> A. That's what I would choose.

Accordingly, there is no genuine issue of material fact that the '100 patent fails to fully support the scope of the claimed invention with respect to the cuff stiffener limitation.

V. CONCLUSION

For the foregoing reasons, Ambu's motion for summary judgment of invalidity for lack of written description should be granted in its entirety, and the Court should hold that asserted claims 1-6 are invalid for lack of written description.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system per Local Rule 5.2 on August 14, 2009.

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